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Award Number: MIPR 1DCB7T1055

TITLE: Using Telemedicine and Wireless Technology to Improve Diabetic Outcomes in Poorly Controlled Patients

PRINCIPAL INVESTIGATOR: Robert A. Vigersky

CONTRACTING ORGANIZATION: Walter Reed Army Medical Center
Washington, DC 20307-5001

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PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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Robert A. Vigersky

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Walter Reed Army Medical Center
Washington, DC 20307-5001

E-Mail: **robert.vigersky@na.amedd.army.mil**

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Table of Contents

MidTerm Overall Evaluation Report

PROPOSAL: 2000000093
TITLE: Using Telemedicine and Wireless Technology to Improve Diabetic Outcomes in Poorly Controlled Patients

ACCOMPLISHMENTS

1. Protocol Approval. The protocol was approved by Department of Clinical Investigation, WRAMC on November 14, 2001. This was the culmination of a long, rigorous, and duplicative process. The time-line for this approval is as follows: Submission to P8 Program – 13 SEP 00 Approval Letter from USAMRMC – 1 DEC 00 Acceptance of Funding – 4 DEC 00 Protocol Writing initiated – 5 DEC 00 MIPR Received – 30 JAN 01 Protocol Submitted to DCI – 8 FEB 01 Protocol Reviewed by CIC and HUC – 6 MAR 01 Revisions Requested by CIC and HUC – 3 APR 01 Revisions Submitted to CIC and HUC – 23 MAY 01, 12 JUN 01, 2 JUL 01 and 5 JUL 01 Submitted to CIRO – 9 JUL 01 Submitted to USAMRMC – 9 JUL 01 Review and Revisions requested by USAMRMC contractor – 19 SEP 01 Revisions Submitted – 26 SEP 01 Further Revisions requested by USAMRMC contractor – 2 OCT 01 Further Revisions Submitted – 25 OCT 01 Acceptance by USAMRMC – 4 NOV 01 Final DCI acceptance – 14 NOV 01

2. Contract and Receipt of Deliverables from HealthSentry The contract for the hardware/software services was put up for bid in FEB 01 and HealthSentry Technology was selected as the vendor in MAR 01. The contract was signed in APR 01. Over the subsequent 8 months, we have worked closely with them in directing the provision of the contract deliverables. They have provided the following deliverables included in the contract: Patient Training Manuals Provider Training Manuals Hardware - Roche Modems, Computer Cables, WebTV Equipment, and customized remote glucose Software - Modification of HealthSentry.net Diabetes Monitoring Service website for WRAMC use, Diabetes Management software development

3. Publications We did a poster presentation (Abstract #112)of the protocol's hypothesis and design entitled: "Using Telemedicine and Wireless Technology to Improve Diabetic Outcomes in Poorly Controlled Patients" at the Annual Meeting of the American Telemedicine Association on 3 JUN 01.

PI's Accomplishment Evaluation: : Project accomplishments are close to proposal

PROBLEMS

Delays in Protocol Implementation 1. As noted in the above time line, it has taken over 15 months since the time of submission of the proposal and over10 months since receipt of the funds to recruit the first patient. 2. This protocol was written with Donna Thomas-Wharton, Ph.D. candidate, who acted as the project officer and was to use the development of the protocol and its results as partial fulfillment of her Ph.D. Because of the delays, she resigned on 12 OCT 01. 3. A new project officer, Tyrone Anderson, was hired and started on 19 DEC 01.

PI's Problem Area Evaluation: : Project has encountered significant problems/issues

LIFE-CYCLE

The plans of the project have not changed although the time line clearly has. Patient recruitment and implementation should be substantially easier at this point in time since from the time of the submission of this proposal to the present, the Diabetes Institute substantially expanded. It has hired 7 nurse practitioners, 1 part-time endocrinologist, and 4 support personnel who have been fully integrated into the Walter Reed Health Care System. The providers have been participating in the software development and website modification. The time line for completion has been established as follows: 31 MAR 02 – cessation of patient recruitment 30 SEP 02 – completion of all 6-month trials of technology 30 OCT 02 – data analysis 30 NOV 02 – preparation and submission of abstracts to the Endocrine Society and/or American Diabetes Association annual meeting (JUN 03) 31 DEC 02 – preparation and submission of a manuscript

PI's Life-Cycle Evaluation: : Project encountered some problems/issues

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DELIVERABLES

See above for academic intents. Based on results of the study, we intend to incorporate one or more of these technologies into the standard of care for our patients with Diabetes Mellitus. Furthermore, it is our intent to expand the website application to all patients with Diabetes Mellitus and their providers within NARMC.

PI's Deliverables Evaluation: : Deliverable is on schedule per Proposal

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Expenditures

Element of Resource (EOR)	1ST Quarter Oct 1 - Dec 31	2nd Quarter Jan 1 - Mar 31
Travel 2100	$1,000.00	$0.00
Shipping 2200	$0.00	$0.00
Rent & Communications 2200	$0.00	$0.00
Contract for Services 2500	$50,015.00	$21,015.00
Supplies 2600	$0.00	$0.00
Equipment 3100	$83,800.00	$30,000.00

Financial Narrative:

Contract for Services include administrative fee of 10% from Telemedicine, WRAMC and 3% from Dept. of Mines. Project officer funds have been depleted because of the delay in implementing the project. However, payment of the new Project Officer will be made with funds initially allocated for a Nurse Practitioner and Data Manager. The remainder of the funds have been used to purchase equipment (WebTV, modems, cables), training manuals, website development, Website/PC support, and software license. Expansion of the use of HealthSentry.net Diabetes Monitoring Service System to the WRHCS, NARMC, and AMEDD will require the purchase of license, the price of which is negotiable but may be up to an additional $225,000. If one of the technologies is successful in improving glycemic control, there will be significant financial implications. There are numerous ways to calculate the economic benefit of better control of diabetes. The most conservative estimate is that there is a savings of $400 per diabetic patient per year if the Hemoglobin A1c (a measure of glycemic control over 3 months) is reduced from 8-10% to under 8%. The projected savings would be about $2.4 million per year for the 6000 patients in the WRHCS.

PI's Financial Evaluation: : Deliverable is on schedule per Proposal

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*** END OF REPORT ***